SPECIFICATION

PLASMA LIPIDS IN-VITRO FILTERING METHOD AND APPARATUS

TECHNICAL FIELD OF THE INVENTION

[0001] The present invention relates to in-vitro blood plasma lipids filtering method and apparatus, and more particularly relates to in-vitro blood plasma lipids filtering method and apparatus.

BACKGROUND OF THE INVENTION

[0002] It is well known, with increasing living standards, the high-blood lipids has already become a universal disease. According to World Health Organization statistics, all over the world there are approximately 15 million mortality cases every year from cardio-cerebral-vascular diseases, which is more than 50% of the total mortality rate.

[0003] The blood lipids are referring to the fat content of the blood, usually referring to the cholesterol and triglyceride. The blood lipids are important to the human body growth, especially in cell formation and body metabolism. The hyperlipidemia is referring to the excessively high blood level of cholesterol (TC), the triglyceride (TG), or the low-density lipoprotein cholesterol (LDL-C), in modern medical terminology referred to as abnormal blood lipids.

[0004] The abnormal blood lipids lead to atherosclerosis, an important dangerous factor of coronary disease. Famous FRAMINGHAM studies proven that lowering TC 1% reduces 2% of CVE. Reducing TC and LDL-C is important in controlling and preventing coronary diseases. In brain infarction patients, patients with Blood Hypervisicosity Syndrome (HBS) formation rate reaches as high as 63.7%.

[0005] Regarding diseases caused as a result of high blood lipids, the drug treatment thus far has proven to be unsatisfying. At present, with biological technology progression, leading to the filtering method using in-vitro blood plasma to prevent and control diseases caused by high blood lipids (cholesterol, triglyceride, low-density lipoprotein and chyle-cholesterol). In-vitro blood plasma filtering method is gradually becoming the direction of research and development in biological and medical science.

[0006] In order to reduce blood lipids quickly, lipid reduction apparatus has already obtained clinical use. However, an apparatus of such kind usually uses physical chemistry method to carry on the lipid reduction process. Lipid reduction via lipid reducing apparatus is more effective and direct, in comparison with drug treatment to reduce blood plasma lipids. An apparatus of such kind is still unsatisfactory, and certainly has safety concerns.

[0007] At present, the main clinical use is a German apparatus, and this lipid reduction apparatus first treats the patient's blood plasma by a chemical process to adjust the PH value, and then filters the blood plasma lipids after the chemical precipitation process. Utilizing this apparatus to filter the blood plasma lipids usually takes three hours to complete. Moreover, after two filtering processes, the lipid reduction effect is also reduced to only 30%-50%. Especially, after chemical processing, the hemoglutination in blood plasma may be damaged or lost as a result. In addition, this apparatus is currently very expensive, and the operational procedure is complex.

SUMMARY OF THE INVENTION

[0008] The present invention provides an in-vitro blood plasma lipids filtering method, which overcomes the above-mentioned technical difficulty and insufficiency.

[0009] An objective of the present invention is to resolve and provide a technology which is more direct and effective, and also provides a safe blood plasma lipids removal procedure.

[0010] In accordance with an aspect of the present invention, the present invention provides an in-vitro blood plasma lipids filtering method, comprising the following steps: collecting the blood and separating out the blood plasma, carrying out saline solution treatment of the apparatus, carrying out blood plasma peristalsis, temperature and pressure control, passing the blood plasma through to screening procedure, collect post-filtered blood plasma back into the blood.

[0011] During the filtering process, the collected blood is gradually treated and separated out. Each separation separates out about 150-250 milliliters of the blood plasma. The blood plasma passes through the screening procedure about 20-30 milliliters every minute. In the above-described screening procedure, pressure is controlled below 60KPa. Adding heat to the blood plasma and the temperature is just about equal to the body temperature.

[0012] The above described blood plasma lipids screening procedure comprises three thin films or membrane, wherein a first film may be a membrane which has filter aperture pores of about 0.3 to 0.65 microns and comprises a lipid absorptive material; a second film is a

membrane which has filter aperture pores of about 0.3 microns; and a third film is a membrane which has filter aperture pores of about 0.2 microns and is made of nylon as the base material. In between the second and third thin films, there contains one or multiple layers of the first thin film. The lipid absorptive material used is the silicon oxide pellets.

[0013] Another objective of the present invention is to provide an in-vitro plasma lipids screening procedure technology, which is more direct and effective, and also provides a safe blood plasma lipids removal procedure.

[0014] In accordance with an aspect of the present invention, the present invention provides an in-vitro blood plasma lipids screening procedure, comprising: a blood collecting device, a blood separating device, a pre-filtered blood plasma bag, a blood lipids screening procedure, a post-filtered blood plasma bag as well as the blood plasma feedback device. These devices are connected via pipelines and/or tubes, and the pipelines and tubes are also connected with a peristaltic pump. In addition, pressure and temperature control devices are installed among the pipelines and tubes. The in-vitro blood plasma lipids screening procedure also includes saline solution treatment bag and waste saline solution bag. The saline solution treatment bag is connected to an outlet of the pre-filtered blood plasma bag, and the waste saline solution bag is connected to an entrance of post-filtered blood plasma bag.

[0015] The above-mentioned pre-filtered blood plasma bag contains an automatic weight or volume detector device, and transmits a signal when the blood plasma bag is full to the blood separating device or the blood collecting device, thereby triggers a stop response. The volume of the pre-filtered blood plasma bag is about 150-250 milliliters.

[0016] The above-mentioned pressure control device can read out the current pressure inside the pipeline tube. The pressure control device controls the pressure to be below 60KPa. The rotational speed of the peristaltic pump is controlled to maintain a flow rate of the blood plasma at about 20-30 milliliters every minute.

[0017] The above-mentioned temperature control device is installed within the screening procedure, so that the highest heating temperature is controlled at 38°C.

[0018] The above described blood plasma lipids screening procedure comprises three thin films or membrane, wherein a first film may be a membrane which has filter aperture pores of about 0.3 to 0.65 microns and comprises a lipid absorptive material; a second film is a type of membrane which has filter aperture pores of about 0.3 microns; and a third film is a membrane which has filter aperture pores of about 0.2 microns and is made of nylon as the base material.

In between the second and third thin films, there contains one or multiple layers of the first thin film. The lipid absorptive material used is the silicon oxide pellets.

[0019] The present invention can chemically remove the blood lipids, and thus is suitable to use in cases of high blood lipids diseases that are not suitable for drub treatment, such as in high cholesterol blood level, hypertriglyceridemia, high-and-low-density lipoproteinemia, Blood Hypervisicosity Syndrome (BHS), and so on. The present invention is obviously effective in removing blood fibrinogen, preventing stroke, and reducing blood viscosity. The present invention can remove about 50% of blood lipids in one time filtering, and moreover, may be repeatedly carried out numerous times.

[0020] The present invention utilizes the pure physics affinity with the natural adsorption method; therefore, the present invention is safer, securer, and more tolerant. During treatment, patients generally have not shown obvious discomfort. In addition, the treatment time is short and patients usually spend approximately two hours per treatment. Moreover, the operational procedure is simple and requires minimal supervision of specialists or special trainings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] A detailed description will be given with respect to a preferred embodiment of the present invention and the best mode for carrying out the present invention for further explanation to this invention with reference to the sole drawing, FIG. 1, which is a schematic illustration showing an implementation example of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT AND THE BEST MODE OFR CARRYING OUT THE PRESENT INVENTION

[0022] The present invention will be further described in details in conjunction with the accompanying drawing. Referring to FIG.1, which is a schematic illustration showing an implementation example of the present invention, a blood separating device is first employed, which utilizes a centrifugal separation method to separate the blood plasma from a patients' blood collecting bag. Other cellular components are feedback to the patients in a feedback loop. The separated blood plasma enters a pre-filtered blood plasma bag, and a saline solution bag for pre-treating the device and tubes is connected to the device at an outlet of the pre-filtered blood plasma bag.

[0023] The pre-treatment saline solution or blood flows through the pipeline tubes to the peristaltic pump. The peristaltic pump provides power and pressure for the in-vitro loop device. An end terminal of the in-vitro loop device has an adjustable pressure control to adjust and control pressure, ensuring a safer and comfortable treatment process. Then the pipeline tube is connected to plasma lipids screening procedure, and the screening procedure filter membrane is evenly distributed with massive functional particles. Post-centrifugal mixed-particles blood plasma flows through the filter membrane so that TC, TG, LDL and so on, are firmly attracted and attached on the filter membrane. Thereby, the unclouded, thus purified blood plasma flows out screening procedure, and enters through the pipeline tube into post-filtered blood plasma bag. The post-filtered blood plasma bag entrance is connected with a pipeline tube to the waste saline solution bag. During saline solution treatment, the pipeline tube to post-filtered blood plasma bag connection is shut-off, so that post-filtered blood plasma is not mixed with the saline solution, and the treatment saline solution flows to the waste saline solution bag. During the blood filtering process, shutting-off the pipeline to waste saline solution bag will also ensure that the post-treatment blood plasma flows through to the post-filtered blood plasma bag. The blood plasma passes through a temperature control device to maintain a constant temperature of the blood plasma. The temperature-controlled blood plasma is then looped back to the body via a blood plasma feedback device.

[0024] In the above-mentioned device, the blood colleting device collects the blood and also allows the blood cellular components to be fed back in a loop. Therefore the device may be a generic blood-collecting device, or the device may be specially designed double-barrel single-needle device. Certainly, the device may be designed to independently draw blood and with the feature of feedback pipeline tube and needle. However, a device like such will require that the patients to be inserted twice with needles, and presumably will increase pain on the patients.

[0025] The separated blood plasma flows into a pre-filtered blood plasma bag. The said blood plasma bag has a certain volume or weight, so that when the blood plasma inside the blood plasma bag achieves a certain volume or weight, the blood separating device and the blood collecting device will stop. In some implementation examples, the blood plasma bag has an automatic volume or weight detection device, which transmits a signal when the blood plasma is full, so that the blood separating device and the blood collecting device are triggered to shut-off. Generally, a typical volume of a blood plasma bag is about 200 milliliters. The said volume satisfies filtering efficiency and ensures that patients feels comfortable, and causes no damage to danger to the patients.

[0026] The present invention also has a saline solution treatment device, the saline solution treatment bag parallel with the pre-filtered blood plasma bag are connected to the

lateral device. Moreover, just prior to the entrance of the post-filtered blood plasma bag, there exists a pipeline tube connecting to the waste saline solution bag. Before the start of the apparatus set, the blood plasma bag is shut-off, the saline solution inside the saline solution treatment bag flushes the pipeline tube and the device, and the post-flushing saline solution enters the waste saline solution bag. Closure of the saline solution bag is made after the flushing is completed. The blood plasma bag is open to allow blood plasma to flow into pipeline tube. The flushing of saline solution is due to the following considerations. First, typical medical devices and pipeline tubes are disinfected daily or after each use. These disinfectants, such as Oxirane, are generally harmful to the human body, and can remain in the pipeline tube in varying degrees. The saline solution treatment can wash off these harmful residues. Next, the saline solution treatment can be used to check the system's seal-proof quality, in order to guard against leakage occurring during process. Again, after the closure of the saline solution bag, there may be saline solution remaining in the pipeline tube and the apparatus, and the residual saline solution can be used to supplement patient's blood capacity. After post-filtration process, the blood plasma is exchanged to prevent the loss of blood plasma. The saline solution treatment bag and the waste saline solution bag may also be installed in other parts of the apparatus that can totally wash-out the pipeline tube and device.

[0027] Blood plasma in the pre-filtered blood plasma bag flows to the peristaltic pump, and the peristaltic pump provides the pipeline tube with power for liquid movement. In the back of the peristaltic pump, there is a pressure control device, which can read out the current pipeline tube pressure. In some implementation examples, the pressure control device may also adjust the rotational speed of the peristaltic pump. The peristaltic pump rotational speed produces flowing power for the blood plasma, and the blood plasma later during screening procedure is subject to resistance and in turn induces pressure buildup. The pressure, if too large, may harm the apparatus, and simultaneously can also cause the patient to feel ill. However, the peristaltic pump rotational speed, if too slow, causes the blood plasma flow speed to be slow, and can lead to lengthening the filtration time. Numerous implementation examples prove that when the speed of flow is about 20-30 milliliters per minute, the lipid reduction is more effective. Therefore, general peristaltic pump rotational speed is set in advance at this level. However, due to the fact that some patients' blood plasma density is higher, and may be more difficult to pass screening process, and thus may induce tremendous pressure. When the pressure achieves a level which could possibly harm the apparatus or make the patients feel ill, the pressure control device will indicate this pressure value, and the monitoring staff can reduce the peristaltic pump speed to reduce pressure. When the pressure control device can control the peristaltic pump rotational speed, the process will be able to complete automatically. Therefore, the pressure control can be done by a simple pressure gauge or an automatic velocity regulation system comprising a pressure sensory device and speed controlled peristaltic pump. In an example of the present invention, the

pressure marginal value is about 60KPa. Because pressure production and density level of blood plasma are related, through monitoring reading value on the pressure control device, patient's blood density and condition may be determined.

[0028] The blood plasma, after peristaltic pump process, enters the blood plasma lipids screening procedure. The blood plasma lipids screening procedure is composed of multi-layers of thin film membranes, of which a first film may be a membrane which has filter aperture pores of about 0.3 to 0.65 microns and comprises a lipid absorptive material. The first membrane may attract the fatty contents in the blood plasma, and the lipid absorptive material may be of the silicon oxide pellet. In addition, the first membrane filters out other impure particles that are bigger than the filter pores. A second film is a membrane which has filter aperture pores of about 0.3 microns. The second membrane can filter out bacterium and chyle-lipoprotein, because bacterium and chyle-lipoprotein have diameters greater than 0.3 microns. A third film is a membrane which has filter aperture pores of about 0.2 microns and is made of nylon as the base material. The third membrane filters out any and all foreign particles generated from the first and second filtering processes, such matters like thin film wood-pulp material or adsorptive particles.

[0029] The use and number of membrane layers depend on the adsorptive ability and the volume of blood to be filtered must be taken into consideration together. That is, if one layer is insufficient, and multiple layers may be considered to use in stead. In addition, other lipid adsorptive membranes may be placed in between the above-mentioned second and third membranes to make up the insufficiency of the first, second, or third membranes.

[0030] The blood plasma, after filtering process, flows into the post-filtered blood plasma bag and further goes through the blood plasma feedback device and is fed back to the patients. A temperature control device located on the pipeline tube or the apparatus maintains that the blood plasma is at a temperature approximately close to the body temperature. The advantage is that patients are as close to natural condition as possible and thus are comfortable. This temperature control device may be a heating plate with the highest heating temperature controlled at about 38°C. The temperature control device may be placed any where in the pipeline tube or the device which is suitable for heating. The optimal location of the hot plate is suggested in the screening procedure.

[0031] It is to be understood, however, that even though numerous characteristics and advantages of the present invention have been set forth in the foregoing description, together with details of the method and function of the invention, the disclosure is illustrative only, various modifications and changes may be made by persons skilled in this art, especially in arrangement of parts within the principles of the invention to the full extent indicated by the broad general meaning of the terms in which the appended claims are expressed. It is

intended that the present invention should not be limited to the particular forms, and that all modifications and changes which maintain the spirit and realm of the present invention are within the scope as defined in the appended claims.